OCT 2 4 2001

K012990

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BioCore Medical Technologies, Inc.

State-of-the-Art Biomaterials Technologists

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Silver Spring, Maryland 20904
U.S.A.

510(k) Summary

"This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92"

"The assigned 510(k) number is: K012990

Submitter's Name and Address:

BioCore Medical Technologies, Inc.
11800 Tech Rd. Suite 240
Silver Spring, MD 20904

Contact Person, Telephone and Fax Number:

Ajay Kumar, VP of Operations
Phone: (301) 625-6818
Fax: (301) 625-6819

Date the Summary was Prepared:

September 19, 2001

Device Names:

Proprietary Name:	Collatek® Powder
Common Name:	hydrocolloid wound powder
Classification Name:	wound and burn dressing

Predicate Device:

Trade name:	hyCURE® Powder
Company:	Hymed Group Corporation
Trade name:	Comfeel® Powder
Company:	Coloplast Group, Ltd.
Trade name:	Medifil® Particles
Company:	BioCore Medical Technologies, Inc

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Device Description:

Collatek® Powder is a sterile, disposable, single use, wound-dressing device for the management of dermal lesions and injuries. It is to be used to fill in full and partial thickness wounds with moderate to heavy exudate. Collatek® Powder is able to conform to any wound site.

Collatek® Powder is a hydrophilic, hydrocolloid wound-powder with a collagen base. Collatek® Powder's collagen is an insoluble fibrous type I bovine collagen derived from cowhide. Collatek® Powder will be available in a 1 gram size packet, additional sizes may be introduced at a later time

Basis for Substantial Equivalence:

1. Indications for Use

Collatek® Powder will be used to manage full thickness and partial thickness wounds with moderate to heavy exudate. Collatek® Powder is intended for use on: pressure ulcers (stages I-IV), venous ulcers, ulcers caused by mixed vascular etiologies, diabetic ulcers, first and second degree burns, donor sites and other bleeding or secreting dermal lesions and injuries.

Collatek® Powder's indications for use are comparable to the commercially available predicate devices (hyCURE® Powder, Comfeel® Powder and Medifil® II Particles).

2. Instructions for Use

Collatek® Powder's manner of use is similar to other wound care products. First, cleanse the wound. Second, apply medication to wound as indicated. Third, apply Collatek® Powder to the wound surface. Lastly, Cover with absorbent dressing and change dressing as needed in accordance with labeling instructions.

Collatek® Powder's instructions for use are comparable to the commercially available predicate devices (hyCURE® Powder, Comfeel® Powder and Medifil® II Particles).

3. Technological Characteristics

Collatek® Powder is a hydrocolloid wound dressing prepared from fibrous type I bovine collagen. Collagen protects the wound bed and newly formed granulation tissue by formation of a protective covering that is conducive to wound healing.

Collatek® Powder is designed to be a dry particulate product, this gives Collatek® Powder the advantage of being able to absorb many times its own weight in liquid exudate and the ability to conform to any wound site. For this reason, Collatek® Powder is designed for use on moderate to high exudating wounds with simple and complex wound irregularities.

Collatek® Powder is analogous in design as the commercially available predicate devices (hyCURE® Powder, Comfeel® Powder and Medifil® Particles).

4. Materials

The material used for Collatek® Powder consists of fibrous Type I bovine collagen. Collagen is also the material use in manufacture of hyCure and Medifil Particles. Therefore, Collatek is similar to predicate devices in terms of materials used.

5 Safety

Biocompatibility testing has confirmed that Collatek® Powder meets requirements as stated in FDA's Blue Book Memorandum G95-1 and ISO 10993. Results are given in Appendix K.

6. Sterility and Packaging

Collatek® Powder will be packaged as a single use, disposable foil packet. The package and its contents will be sterilized using electron beam radiation. Collatek® Powder will be sterilized to a SAL index of 10^{-6}. The sterility of Collatek® Powder will be ensured by validation in accordance with ANSI/AAMI/ISO 11137-1994.

Conclusion

Collatek® Powder is equivalent in design, function, materials and intended use and is therefore substantially equivalent to the commercially available predicate devices: hyCURE® Powder (Hymed Group Corporation), Comfeel® Powder (Coloplast Group, Ltd.) and Medifil® II Particles (BioCore Medical Technologies, Inc.). We therefore submit that Collatek® Powder is substantially equivalent to hyCURE® Powder, Comfeel® Powder and Medifil® II Particles.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 4 2001

Mr. Ajay Kumar
Vice President of Operations
BioCore Medical Technologies, Inc.
11800 Tech Road
Suite #240
Silver Spring, Maryland 20904

Re: K012990
Trade Name: Collatek Powder
Regulatory Class: Unclassified
Product Code: KMF
Received: September 6, 2001

Dear Mr. Kumar:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K012990

Device Name: Collatek Powder

Indications for Use:

Collatek Powder may be used in the management of:

- Partial and full thickness wounds
- Pressure (stage I-IV) and venous ulcers
- Ulcers caused by mixed vascular etiologies
- Venous stasis and diabetic ulcers
- Ist and 2nd degree burns
- Cuts, abrasions and surgical wounds

Contraindications:

Collatek powder should not be used on persons sensitive to bovine products.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K012990

Prescription Use X OR Over-The-Counter-Use
(Per 21 CFR 801.109) (Optional Format 1-2-96)